



The Wright Center for Graduate Medical Education
Institutional Review Board
WCGME – IRB

Request for Human Subjects Research Determination
(Non-FDA Regulated Research)

Project Title:	Date:
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I. Applicant Information

Name:	
<input type="checkbox"/> Faculty <input type="checkbox"/> Student <input type="checkbox"/> Other:	Dept./Unit:
Address:	
Email:	Phone:

Faculty/Resident Advisor (if appropriate) NA

NOTE: A Faculty Advisor is required if the applicant is a student, resident or fellow.

Name:	Department/Unit:
Address:	
Email:	Phone Number:

II. PROJECT DESCRIPTION

Summary. Provide a summary of the proposed project. The summary should summarize the subjects involved, the objectives of this project and the procedures to be used. *Alternatively, a narrative or protocol may be attached and submitted.*

III. QUALITY IMPROVEMENT, PROGRAM EVALUATION ASSESSMENT

QI and research, and Program Evaluation and research, are not mutually exclusive terms, sometimes an activity can be both. The questions in this section help differentiate whether an activity is purely QI or Program Evaluation, or if the activity includes a research component. Complete this section if you believe your activity is Quality Improvement or Program Evaluation; otherwise, skip the questions in this section and move forward to **Section IV**.

Quality Improvement (QI) - involves systematic activities that are designed and implemented by an organization to monitor, assess, and improve the quality of its services, processes, or programs.

Program Evaluation – individual systematic activities conducted to assess how well a program is working and why.

1. The methods used in an activity can help distinguish whether a project is QI, program evaluation, or research. Please answer the following:
 - a. Does the project involve randomization, blinding, or assignment into two or more subject groups or arms?
 Yes. These methods are more consistent with research than quality or program evaluation
 No
 - b. Does the activity use Quality Improvement methods such as FADE, PDSA, Six Sigma, CQI, or TQM?
 Yes. These methods are more consistent with quality improvement than research
 No
2. Similarly, the intent of the activity is informative to the determination.
 - a. Evaluate or improve clinical care or a process, practice, or program at TWC?
 Yes **No**
 - b. Only be applied to populations, or inform practice within the target population or TWC?
 Yes **No**
 - c. Implement an evidence-based practice, process, or program and evaluate whether it functions as intended within TWC or with the local target population?
 Yes **No**
 - d. Evaluate an existing practice, process, or program to determine if it is functioning as intended?
 Yes **No**
 - e. Establish scientific evidence, or build upon early existing evidence, in support of a new or modified practice, process, or program?
 Yes **No**
3. Based upon the scientific literature, is it expected that all participants will benefit from the practice, process, or program or is this unknown?
 Yes **No** **Unknown** **NA to this proposal**
4. Are there any risks to participants anticipated as a result of inclusion in the program or initiative?
 Yes **No**
If Yes:
 - a. Does this represent an overall increase or decrease in risk exposure?
 - b. What steps are being taken to minimize those risks?
5. Please use this space to explain if you were unable to answer any of the above questions or provide additional information that may be relevant to the determination:

Once you've completed the questions in this section, move forward to Section IV.

IV. COMMON RULE DETERMINATION

1. Is the activity “research”?

As defined by Department of Health and Human Services (DHHS) regulations: “Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” [45 CFR 46.103\(d\)](#)

- a. Does the activity involve a **systematic investigation** (i.e., an activity that involves a prospective plan which incorporates data collection, either quantitative or qualitative, and data analysis to answer a question)?

Yes No

- b. Is the activity is designed to develop or contribute to **generalizable knowledge** (i.e., the evidence base for the process, practice, or program is not yet firmly established or accepted; and, the activity is not dependent on the unique characteristics of the target population or system in which it will be implemented)?

Yes No

2. Does the activity involve “human subjects”?

- a. Will you obtain information or biospecimens through **intervention** with living individuals? *This includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment, that are performed for research purposes.*

Yes No

- b. Will you obtain information or biospecimens through **interaction** with living individuals? *This includes communication or interpersonal contact between researchers and subjects, including indirect interaction such as via a web-based survey.*

Yes No

- c. Will you obtain, use, study, analyze, or generate **Identifiable Private Information** about living individuals and/or a **Biospecimen**?

Private Information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical or education record).

Private Information means that the identity of the subject is or may readily be ascertained by the investigator or associated with the information. Note: When data or specimens are coded, and the investigator has access to the key or another means to re-identify, the data is identifiable. Consult with the IRB Office for questions on this topic.

Identifiable Private Information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

An **Identifiable Biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Yes No

